UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,162	03/16/2001	Manuela Martins-Green	407E-000500US	5788

22798 7590 01/11/2002

LAW OFFICES OF JONATHAN ALAN QUINE
P O BOX 458
ALAMEDA, CA 94501

EXAMINER
DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
1647	7

DATE MAILED: 01/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/811,162	MARTINS-GREEN ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-86* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-86* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8,19, 20 drawn to polypeptide fragment and the pharmaceutical compositions, classified in class 530, subclass 300.

II. Claims 9-18, drawn to isolated nucleic acid, vector and host cell, classified in class 435, subclass 69.1.

III. Claims 21-23, 39-53,55 drawn to the nucleic acid pharmaceutical composition and the method of inducing differentiation of fibroblast to myofibroblasts *in vivo* and *in vitro* with an effective amount of a nucleic acid, classified in class 514, subclass 44.

IV. Claims 24-38,54, drawn to the method of inducing differentiation of fibroblast to myofibroblasts *in vivo* and *in vitro* with an effective amount of a polypeptide, classified in class 514, subclass 2.

V. Claims 56-62, drawn to the method of inducing differentiation of fibroblast to myofibroblasts *in vivo* and *in vitro* with an effective amount of an inhibitor of a differentiation-inducing chemokine, class dependent on inhibitor.

VI. Claim 56,57,63,64, drawn to the method of inducing differentiation of fibroblast to myofibroblasts *in vivo* and *in vitro* with an effective amount of an antibody that specifically binds the CXC chemokine, classified in class 424, subclass 130.1.

VII. Claims 65-68,70-72, drawn to a method of screening for an agent comprising detecting the level of protein, classified in class 435, subclass 7.2.

VIII. Claims 65-69,71,72, drawn to a method of screening for an agent comprising detecting the level of mRNA, classified in class 436, subclass 501.

IX. Claims 73-76,79,80, drawn to a method of prescreening for an agent comprising detecting specific binding of a test agent to a chemokine nucleic acid, classified in class 435, subclass 6.

X. Claims 73-75, 77-80, drawn to a method of prescreening for an agent comprising detecting specific binding of a test agent to a chemokine protein, classified in class 435, subclass 7.1.

XI. Claims 81-86, drawn to a method of prescreening for an agent said method comprising detecting specific binding of a test agent to a chemokine receptor, classified in class 435, subclass 7.8.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. §806.06 for inventive groups that are directed to <u>different</u> products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons: Groups I-II are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. The protein of Group I can be prepared by

processes which are materially different from recombinant DNA expression of Group II, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Group II can be used other than to make the protein of Group I, such in gene therapy or as a probe in nucleic acid hybridization assays.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. §806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups III-XI are directed to methods that recite structurally and functionally distinct elements, are not required one for the other, and/or achieve different goals. Therefore, a search and examination of all nine methods in one patent application would result in an undue burden, since the searches for the three methods are not co-extensive, the classification is different, and the subject matter is divergent.

Inventions I (product) and IV (process of use); II (product) and III (process of use) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group I can be used in methods to make antibodies and the product of Group II can be used in polymerase chain reactions.

Claim 62 is generic to a plurality of disclosed patentably distinct species (condition) comprising keloid formation, pulmonary fibrosis, scleroderma and cancer. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

In addition, some of the Groups read on patentably distinct sequences (SEQ ID NO:). Each sequence is patentably distinct because they are composed of unrelated or diverse sequences, different coding regions and/or imparts structural and functional differences. For an elected Group drawn to an amino acid sequence (SEQ ID NO:), Applicant must further elect a single amino acid sequence. Applicant must either elect SEQ ID NO:8 and 9 (IL-8) **or** SEQ ID NO:10 (cCAF) **or** SEQ ID NO:11 (MGSA). This is not a species election but a further election of a group.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements, and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on Mondays-Fridays 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 308-2742 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

RMD

RMD
January 8, 2002

ELIZABETH KEMMERER
PRIMARY EXAMINER